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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/381,372	09/20/1999	TOSHIKAZU KAWAI	038788.48236	3875

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EXAMINER	
KEYS, ROSALYND ANN	
ART UNIT	PAPER NUMBER
1621	

DATE MAILED: 07/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/381,372	KAWAI ET AL.	
	Examiner	Art Unit	
	Rosalynd Keys	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 12-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 12-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1-9 and 12-18 are pending.

Claims 1-9 and 12-18 are rejected.

Claims 10 and 11 are cancelled.

Continued Examination Under 37 CFR 1.114

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 10, 2006 has been entered.

Claim Rejections - 35 USC § 103

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1-9 and 12-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawai et al. (EP 0 703 450 A1).

Kawai et al. teach removal of acid component and non-reacted HFIP from SEVOFLURANE by contacting the SEVOFLURANE with water or an alkali aqueous solution (see entire disclosure, in particular page 3, line 58 to page 4, line 7; and examples 1 and 6). The alkali metal and alkaline earth metal compounds suitable are disclosed on page 4, lines 1-3). The concentration of alkali aqueous solution is disclosed as not critical. However from 0.01 to 10 wt% is convenient for use

(see page 4, lines 4 and 5). The treatment temperature is disclosed to be usually about from 0 to 60°C (see page 4, line 5).

Kawai et al. differ from the instant claims in that Kawai et al. do not teach utilizing SEVOFLURANE that contains not more than 0.25% by weight or 1% by weight of HFIP.

One having ordinary skill in the art at the time the invention was made would have found it obvious to obtain a SEVOFLURANE having the claimed amounts of HFIP, since Kawai et al. teach that the conversion of HFIP can be varied by modifying the amount of hydrogen fluoride and (para)formaldehyde utilized as reactants (see page 3, lines 39-48). The skilled artisan would have been motivated to obtain a SEVOFLURANE having the claimed amounts of HFIP, since SEVOFLURANE is the desired product and in chemical synthesis it is usually advantageous to obtain the desired product in as high a yield as possible. In the case of Kawai et al. it would be advantageous, since it is taught that SEVOFLURANE has use as an inhalation anesthetic (see page 2, lines 12).

Kawai et al. further differ from the claimed invention in that Kawai et al. do not teach that one must use a basic substance in an amount providing a chemical equivalent ratio of said basic substance to HFIP being within a range of not less than 1. Kawai et al. do however teach that use of an alkali aqueous solution would allow one to remove non-reacted HFIP from SEVOFLURANE.

One having ordinary skill in the art at the time the invention was made would have found it obvious to select an amount of the basic substance that would allow the artisan to achieve the desired result, i.e. removal of HFIP.

Response to Arguments

5. Applicant's arguments filed July 10, 2006 have been fully considered but they are not persuasive.

The Applicants argue that the combination of Ryan and Kawai does not reasonably suggest

contacting crude SEVOFLURANE having a critical amount of HFIP (:0.25 wt.%) with a basic aqueous solution to remove HFIP from the crude SEVOFLURANE. The Examiner disagrees. Both Kawai and Ryan teach that one can vary the amount of HFIP converted during production of SEVOFLURANE, therefore the skilled artisan would reasonably expect that the claimed amount of HFIP can be obtained by carrying out the methods disclosed by Ryan and Kawai for obtaining SEVOFLURANE (see page 3, lines 39-45 of Kawai and page 2, lines 22-31 of Ryan). Kawai further teach removal of non-reacted HFIP from the crude SEVOFLURANE using an aqueous alkali solution.

The Applicants argue that the cited prior art does not teach or suggest a method of removing HFIP from crude SEVOFLURANE that results in such a dramatic reduction in the HFIP concentration. This argument is not persuasive because the claims do not require reducing HFIP to 1/2500th of the original content. The claims require removal of HFIP from SEVOFLURANE. Kawai et al. accomplishes such removal.

The Applicants argue that based upon Ryan one having ordinary skill in the art would not be motivated to remove HFIP from an already HFIP free SEVOFLURANE. This argument is not persuasive because the instant claims read upon purification of a SEVOFLURANE, which contains no HFIP. The limitation not greater than about 0.25% by weight and less than about 1% by weight both read upon 0% by weight of HFIP. Nonetheless, the Ryan reference is no longer be applied, since the teaching for which Ryan was relied is taught by Kawai al., i.e., that the amount of HFIP remaining in the SEVOFLURANE can vary depending upon the reaction conditions for producing the SEVOFLURANE.

The Applicants allegations of unexpected results with respect to the use of the claimed amounts of HFIP have been considered, but are not persuasive because the prior art also removes HFIP by contacting sevoflurane with an aqueous alkali solution, thus the removal of HFIP from SEVOFLURANE using an aqueous alkali solution is not an unexpected result. It is true that the applicants show obtaining a different degree of purification when using 0.25% HFIP as compared to 4.91%, which the Applicants

state is the amount in example 6 of Kawai et al. However, it is not enough to show that results are obtained, which differ from those obtained in the prior art: that difference must be shown to be an *unexpected* difference. In re Klosak, 173 USPQ 14 (CCPA 1972). Further, the showing is not commensurate in scope with the claimed invention. The applicants claim an HFIP content of not greater than about 0.25% by weight and less than about1% by weight. However, the declaration only gives data for 0.25%. The data provided therefrom would not allow the skilled artisan the ability to ascertain a trend in the exemplified data, and thus would not allow him to reasonably extend the probative value to the other claimed percentages.

For the above reasons, the Examiner believes that a prima facie case of obviousness has been shown and that the Applicants have not successfully rebutted the prima facie case by showing unexpected results.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is 571-272-0639. The examiner can normally be reached on M-W & F 5:30-8:30 am & 1-5 pm; TH 5:30 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Rosalynd Keys
Primary Examiner
Art Unit 1621

July 18, 2006